

Attachment 4

K091386

510(K) SUMMARY

Numia Medical Technology, LLC
230 Main Street
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Lyndonville, Vermont 05851

OCT - 2 2009

Contact Person:

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Date Prepared: April 1, 2009

Trade Name: MicroFuse Dual Rate Infuser

Common Name: Syringe Infusion Pump

Classification Name: Infusion Pump

Predicate Devices

MicroFuse Dual Rate Infuser

Intended Use

The MicroFuse Dual Rate infuser is intended to be used for the intermittent administration of I.V. medication.

Device Description:

The Numia Medical Technology Dual Rate Infuser, or MicroFuse, is a battery powered, portable device that automates the injection of the contents of a syringe into a patient. The MicroFuse was originally developed and cleared through FDA by Baxa Corporation of Englewood Colorado under K983321. Each MicroFuse has two predetermined rates that are preset at the manufacturing facility. These preset

rates cannot be modified by the user or patient. The MicroFuse is used in conjunction with a sterile syringe, the contents or medication and a sterile administration set for injecting the medication into a patient. It depresses the plunger of the syringe at a controlled, pre-determined rate, delivering the dose in the syringe over an extended period of time. The MicroFuse is offered in three models a standard dual rate model, a rapid infuse model and an extended infuse model. The only difference between these being the pre-determined infusion rates programmed into the device's software.

The MicroFuse System consists of the MicroFuse Dual Rate Infuser and a syringe and administration set. Both syringe and administration sets are sterile and disposable. Since only the accessory syringes and administration sets are in the fluid path, the MicroFuse has no patient contact materials. This also means the device is not provided sterile, nor is it sterilized in the field.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-0609
Silver Spring, MD 20993-0002

Mr. Eric J. Flachbart
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Numia Medical Technology, L.L.C.
230 Main Street
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Lyndonville, Vermont 05851

OCT - 2 2009

Re: K091386
Trade/Device Name: MicroFuse Dual Rate Infuser
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: September 15, 2009
Received: September 24, 2009

Dear Mr. Flachbart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

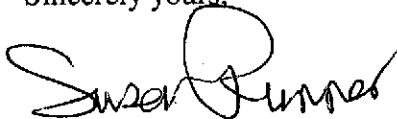
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Susan Runner, D.D.S., M.A.

Acting Division Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K091386

Device Name: MicroFuse Dual Rate Infuser

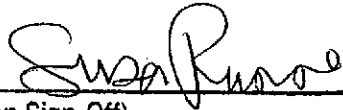
Indications for Use:

The MicroFuse Dual Rate infuser is intended to be used for the intermittent administration of I.V. medication.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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